(8) The rate of tax per cubic yard determined by the California Debris Commission applicable to the particular mine; and

(9) The amount of tax due and payable (cubic yards mined multiplied by the rate of tax per cubic yard).

(c) *Supporting statement.* With each return there must be submitted a supporting statement of the person who made the surveys at the mine for the mining season covered by the return (see § 50.6), stating that such surveys were made in accordance with requirements prescribed by the California Debris Commission.

(d) *Verification of return and supporting statement.* The return and the supporting statement shall be verified by written declarations that they are made under the penalties of perjury.

§ 50.8 Due date and place for filing returns and paying tax.

The return for a taxable year shall be filed with, and the tax shall be paid to, the district director at San Francisco, California, on or before September 30 of the calendar year in which the taxable year ends. The tax is due and payable on such date without assessment by, or notice from, the district director.

PART 51—BRANDED PRESCRIPTION DRUG FEE

Sec.

AUTHORITY: 26 U.S.C. 7805; sec. 9008, Public Law 111–347 (124 Stat. 119).

Section 51.8 also issued under 26 U.S.C. 6302(a).

Section 51.6302–1 also issued under 26 U.S.C. 6302(a).

SOURCE: T.D. 9544, 76 FR 51249, Aug. 18, 2011, unless otherwise noted.

§ 51.1T Overview (temporary).

(a) The regulations in this part 51 are designated ''Branded Prescription Drug Fee Regulations.''

(b) The regulations in this part 51 provide guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs by section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111–148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111–152 (124 Stat. 1029 (2010)). All references in these regulations to section 9008 are references to section 9008 of the ACA, as amended by section 1404 of HCERA. Unless otherwise indicated, all other section references are to sections in the Internal Revenue Code. All references to ''fee'' in these regulations are references to the fee imposed by section 9008.

(c) Section 9008(b)(4) sets an applicable fee amount for each year, beginning with 2011, that will be apportioned among covered entities with aggregate branded prescription drug sales of over $5 million to government programs or pursuant to coverage under such programs. Generally, each covered entity is liable for a fee in each fee year that is based on its sales of branded prescription drugs in the sales year that corresponds to the fee year in an amount determined by the Internal Revenue Service (IRS) under the rules of this part.

§ 51.2T Explanation of terms (temporary).

(a) *In general.* This section explains the terms used in this part for purposes of the fee imposed by section 9008 on branded prescription drugs.

(b) *Agencies.* The term *agencies* means—

(1) The Centers for Medicare and Medicaid Services of the Department of Health and Human Services (CMS);

(2) The Department of Veterans Affairs (VA); and

(3) The Department of Defense (DOD).

(c) *Branded prescription drug*—(1) *In general.* The term *branded prescription drug* means—

(i) Any prescription drug the application for which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)); or

(ii) Any biological product the license for which was submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(2) *Prescription drug.* The term *prescription drug* means any drug that is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

(d) *Branded prescription drug sales.* The term *branded prescription drug sales* means sales of branded prescription drugs to any government program or pursuant to coverage under any such government program. However, the term does not include sales of orphan drugs.

(e) *Covered entity*—(1) *In general.* The term *covered entity* means any manufacturer or importer with gross receipts from branded prescription drug sales including—

(i) A single-person covered entity; or

(ii) A controlled group.

(2) *Single-person covered entity.* The term *single-person covered entity* means a covered entity that is not affiliated with any other covered entity.

(3) *Controlled group.* The term *controlled group* means a group of at least two covered entities that are treated as a single employer under section 52(a), 52(b), 414(m), or 414(o).

(4) *Special rules for controlled groups.* For purposes of paragraph (e)(3) of this section (related to controlled groups)—

(i) A foreign entity subject to tax under section 881 is included within a group under section 52(a) or 52(b); and

(ii) A covered entity is treated as being a member of a controlled group if it is a member of the group on the end of the day on December 31st of the sales year.

(f) *Designated entity*—(1) *In general.* The term *designated entity* means the person that acts for a controlled group regarding the fee by—

(i) Filing Form 8947, ''Report of Branded Prescription Drug Information'';

(ii) Receiving IRS communications about the fee for the group;

(iii) Filing an error report for the group, if applicable, as described in § 51.7T; and

(iv) Paying the fee to the IRS.

(2) *Selection of designated entity*—(i) *Choice of controlled group.* Unless the controlled group is an affiliated group that filed a consolidated return for Federal income tax purposes, the controlled group may select a person as the designated entity by filing Form 8947 in accordance with the form instructions. Among other requirements, the designated entity must state that all the manufacturers or importers of branded prescription drugs that are members of the group have consented to the selection of the designated entity.

(ii) *Requirement for affiliated groups; common parent.* If the controlled group, without regard to foreign corporations included under section 9008(d)(2)(B), is also an affiliated group that filed a consolidated return for Federal income tax purposes, the designated entity is the common parent of the affiliated group as identified on the tax return filed for the sales year. The covered entities in an affiliated group must name the common parent as the designated entity on Form 8947.

(iii) *IRS selection of a designated entity.* If a controlled group does not select a designated entity, the IRS will select a member of the controlled group as the designated entity for the controlled group.

(g) *Fee year.* The term *fee year* means the calendar year in which the fee for a particular sales year must be paid to the government.

(h) *Government programs.* The term *government programs* (collectively ''Programs''), means—

(1) The Medicare Part B program;

(2) The Medicare Part D program;

(3) The Medicaid program;

(4) Any program under which branded prescription drugs are procured by the Department of Veterans Affairs;

(5) Any program under which branded prescription drugs are procured by the Department of Defense; and

(6) The TRICARE retail pharmacy program.

(i) *Manufacturer or importer*. The term *manufacturer or importer* means the person identified in the Labeler Code of the National Drug Code (NDC) for a branded prescription drug.

(j) *NDC*. The term *NDC* means the National Drug Code. The NDC is an identifier assigned by the Food and Drug Administration (FDA) to a branded prescription drug, as well as other drugs. The Labeler Code is the first five numeric characters of the NDC or the first six numeric characters when the available five-character code combinations are exhausted.

(k) *Orphan drugs*—(1) *In general*. Except as provided in paragraph (k)(2) of this section, the term *orphan drug* means any branded prescription drug for which any person claimed a section 45C credit and that credit was allowed for any taxable year.

(2) *Exclusions*. The term *orphan drug* does not include—

(i) Any drug for which there has been a final assessment or court order disallowing the full section 45C credit taken for the drug; or

(ii) Any drug for any sales year after the calendar year in which the FDA approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed, regardless of whether a section 45C credit was allowed for the drug either before, in the same year as, or after this FDA designation.

(3) *FDA marketing approval for treatment of another rare disease or condition*. If a drug has prior FDA marketing approval for the treatment of a rare disease or condition for which a section 45C credit was allowed, and the FDA subsequently gives the drug marketing approval for the treatment of another rare disease or condition for which another section 45C credit was also allowed, the drug retains its status as an orphan drug provided the FDA has never approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed.

(4) *Examples*. The following examples illustrate the rules of this paragraph (k):

Example 1: Allowance of section 45C credit and later FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition. (i) *Facts.* Drug A is a branded prescription drug that was not on the market before 2008. In 2008, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug A. There was no final IRS assessment or court order that disallowed the full credit for Drug A. In 2009, the FDA approved Drug A for marketing for an indication other than the treatment of the rare disease or condition for which the section 45C credit was allowed and this indication was not for another rare disease or condition for which a section 45C was allowed.

(ii) *Analysis.* In 2008 and 2009, Drug A is an orphan drug because: first, it was a branded prescription drug for which a person claimed a section 45C credit and for which that credit was allowed for a taxable year; second, there was not a final assessment or court order disallowing the full credit taken for the drug; and third, before 2009, the FDA did not approve the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. However, Drug A is not an orphan drug for the 2010 sales year or later sales years because in 2009 the FDA approved Drug A for marketing for an indication other than the treatment of the rare disease or condition for which the section 45C credit was allowed and this indication was not for treatment of another rare disease or condition for which a section 45C credit was allowed.

Example 2: FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition and later allowance of section 45C credit. (i) *Facts.* Drug B is a branded prescription drug that was not on the market before 2008. In 2008, FDA approved Drug B for marketing for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. In 2009, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug B. There was no final IRS assessment or court order that disallowed the full credit for Drug B.

(ii) *Analysis.* In 2008, Drug B is not an orphan drug because no section 45C credit was allowed. In 2009, although the covered entity was allowed a section 45C credit for its qualified clinical testing expenses related to Drug B and there was no final IRS assessment or court order that disallowed the full credit, Drug B still is not an orphan drug because the FDA had approved the drug in 2008 for marketing for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed in 2009. Thus, Drug B is not an orphan drug for the 2009 sales year or later sales years.

Example 3: Allowance of section 45C credit and subsequent allowance of section 45C credit with no intervening FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. (i) *Facts.* Drug C is a branded prescription drug that was not on the market before 2007. In 2007, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug C. In 2009, a covered entity claimed an additional section 45C credit for its qualified clinical testing expenses related to Drug C for marketing for the treatment of a rare disease or condition different than the one for which the section 45C credit was claimed in 2007. There was no final IRS assessment or court order that disallowed the full credit for Drug C in 2007 or 2009. The FDA has not approved Drug C for an indication other than the treatment of a rare disease or condition for which a section 45C was allowed.

(ii) *Analysis.* In 2007 and 2008, Drug C is an orphan drug because: first, it was a branded prescription drug for which a person claimed a section 45C credit and for which that credit was allowed for a taxable year; second, there was not a final assessment or court order disallowing the full credit taken for the drug; and third, FDA had not approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. In 2009, Drug C retains its orphan drug status because another section 45C credit was allowed and the FDA did not approve Drug C for marketing for any indication other than the treatment of another rare disease or condition for which a section 45C credit was allowed. Thus, Drug C is an orphan drug for the 2010 sales year.

(l) *Sales taken into account.* The term *sales taken into account* means branded prescription drug sales after application of the percentage adjustment table in section 9008(b)(2) (relating to annual sales less than $400,000,001). See § 51.5T(a)(3).

(m) *Sales year.* The term *sales year* means the second calendar year preceding the fee year. Thus, for example, for the fee year of 2011, the sales year is 2009.

[T.D. 9544, 76 FR 51249, Aug. 18, 2011; 76 FR 59897, Sept. 28, 2011]

§ 51.3T Information requested from covered entities (temporary).

(a) *In general.* Annually, each covered entity may submit a completed Form 8947, ''Report of Branded Prescription Drug Information,'' in accordance with the instructions for the form. Generally, the form solicits information from covered entities on NDCs, orphan drugs, designated entities, rebates, and other information specified by the form or its instructions.

(b) *Due date.* Form 8947 must be filed by the date prescribed in guidance in the Internal Revenue Bulletin.

§ 51.4T Information provided by the agencies (temporary).

(a) *In general.* For each sales year, the IRS will compile a list of branded prescription drugs by NDC using the data submitted on Forms 8947 and in error reports submitted as part of the dispute resolution process (described in § 51.7T) and, after applying appropriate due diligence, will provide this list to the Agencies. The Agencies will provide data to the IRS on branded prescription drug sales during the sales year by Program and NDC. The Agencies will provide data for use in preparing the preliminary fee calculation (described in §§ 51.5T and 51.6T) and may revise or supplement that data following review of error reports submitted as part of the dispute resolution process. The calculation methodology for calculating the sales amounts for each Program, including any reasonable estimation techniques and assumptions that the Agencies expect to use, is described in this section.

(b) *Medicare Part D.* CMS will aggregate the ingredient cost reported in the ''Ingredient Cost Paid'' field and the units reported in the ''Quantity Dispensed'' field of the Prescription Drug Event (PDE) records at the NDC level for each sales year. Only PDE data that Part D sponsors have submitted by the PDE submission deadline (within 6 months after the end of the sales year) and have been approved for inclusion in the Part D payment reconciliation will be included.

(c) *Medicare Part B*—(1) *In general.* CMS will determine branded prescription drug sales under Medicare Part B using the following two data sources:

(i) CMS will use data reported by manufacturers pursuant to section 1847A(c) of the Social Security Act to calculate the annual weighted average sales price (ASP) for each Healthcare Common Procedure Coding System (HCPCS) code for the sales year.

(ii) CMS will use the Medicare Part B National Summary Data File located at *http://www.cms.gov/NonIdentifiableDataFiles/03__PartBNationalSummaryDataFile.asp* to obtain the number of allowed billing units per HCPCS code for claims incurred during the sales year.

(2) *Calculation.* Using the data described in paragraph (c)(1) of this section, CMS will determine branded prescription drugs sales under Medicare Part B as described in paragraphs (c)(3), (4), and (5) of this section.

(3) *HCPCS code; single entity.* For each HCPCS code consisting solely and exclusively of branded prescription drugs (as identified by their respective NDCs) manufactured by a single entity, CMS will multiply the annual weighted ASP by the total number of allowed billing units paid during the sales year to determine the total sales for all NDCs associated with the HCPCS code attributed to Medicare Part B.

(4) *HCPCS code; multiple manufacturers and/or multiple drugs*—(i) *Step one.* For each HCPCS code consisting of a mixture of branded prescription drugs made by different manufacturers and/or a mixture of branded prescription and generic drugs, CMS will determine—

(A) The annual weighted ASP for the HCPCS code;

(B) The total number of allowed billing units paid by Medicare Part B for each HCPCS code during the sales year;

(C) The names of the entities engaged in manufacturing each NDC assigned to the HCPCS code; and

(D) Those entities (if any) identified in paragraph (c)(4)(C) of this section that are manufacturing branded prescription drugs assigned to the HCPCS code.

(ii) *Step two.* Using the information from paragraph (c)(4)(i) of this section, CMS will then do the following:

(A) Calculate the proportion of sales, expressed as a percentage, attributed to each NDC assigned to the HCPCS code by determining the percentage of total sales reported to CMS by each manufacturer of NDC(s) that are assigned to the HCPCS code. For example, if HCPCS code JXXXX contains three drugs with a total of $310,000 sales reported by manufacturers to CMS for the sales year, and $100,000 was reported for Drug A, $200,000 was reported for Drug B, and $10,000 was reported for Drug C, the proportion of sales attributed to each NDC will be 32.26 percent for Drug A, 64.52 percent for Drug B, and 3.22 percent for Drug C; and

(B) For each NDC, multiply the product of the annual weighted ASP and the total allowed billing units paid by Medicare Part B for the HCPCS code by the proportion of sales calculated in paragraph (c)(4)(ii)(A) of this section to determine the sales reportable to the IRS (that is, percentage × (annual weighted ASP × allowed units) = total sales reported to IRS for the NDC). The sales for each manufacturer's NDCs assigned to a HCPCS code are summed and the total sales for each manufacturer's NDCs in a HCPCS code will be reported to the IRS.

(5) *HCPCS code; unable to establish a reliable proportion of sales.* If CMS is unable to establish a reliable proportion of sales attributable to each NDC assigned to the HCPCS code using the method described in paragraph (c)(4)(ii)(A) of this section, CMS will use Medicare Part D utilization percentages in lieu of the proportion of sales determined under paragraph (c)(4)(ii)(A) of this section to perform the calculation described in paragraph (c)(4)(ii)(B) of this section.

(d) *Medicaid.* (1) CMS will determine the branded prescription drug sales for Medicaid as the per-unit Average Manufacturer Price (AMP) less the Unit Rebate Amounts (URA) that CMS calculates based on manufacturer-reported pricing data multiplied by the number of units reported billed by states to manufacturers. This data will be based on the data reported to CMS during the sales year by covered entities and the states for drugs paid for by the states in the Medicaid drug rebate program during the sales year.

(2) For any covered entity identified in the first five (or six) digits of an NDC during any of the four quarters of a sales year, CMS will use the following methodology to derive the sales figures that account for third-party payers, such as Medicare Part B:

(i) Report total dollars per NDC for AMP–URA multiplied by the units reported by a state or states.

(ii) Determine the percentage of the total amount reimbursed that is the Medicaid amount of that reimbursement. For example, if the total amount reimbursed is $100,000, and the Medicaid amount reimbursed is $20,000, then the percentage is 20 percent.

(iii) Multiply the percentage of the Medicaid amount of that reimbursement (in the example in paragraph (d)(2)(ii) of this section, 20 percent) by the dollar figure derived from paragraph (d)(2)(i) of this section (AMP minus URA multiplied by units) to get the new adjusted sales dollar totals.

(e) *Department of Veterans Affairs.* VA will provide, by NDC, the total amount paid (net of refunds and rebates, when they are associated with a specific NDC) for each branded prescription drug procured by the VA for its beneficiaries during the sales year. For this purpose, a drug is procured on the invoice (billing) date. The basis of this information will be national procurement data reported during the sales year by VA's Pharmaceutical Prime Vendor to the VA Pharmacy Benefits Management Service and National Acquisition Center.

(f) *Department of Defense.* The DOD will provide, by Labeler Code, the manufacturer's name, the NDC, brand name, and the amount paid (net of rebates and or refunds) for each branded prescription drug procured by DOD (for DOD programs other than the TRICARE retail pharmacy program) during the sales year. For DOD programs other than the TRICARE retail pharmacy program, a drug is procured based upon the date it was ordered. DOD will provide, by Labeler Code, the manufacturer's name, the NDC, brand name, and the amount paid (net of rebates or refunds) for each branded prescription drug procured by DOD through the TRICARE Retail Pharmacy Program during the sales year. For the TRICARE retail pharmacy program, a drug is procured based upon the date it was dispensed. The amount paid is based on the submitted ingredient cost paid, aggregated by NDC, for eligible TRICARE retail pharmacy claims submitted during the program year, minus any refunds or rebates for the corresponding claims.

§ 51.5T Fee calculation (temporary).

(a) *Fee components*—(1) *In general.* For every fee year, the IRS will calculate a covered entity's total fee as described in this section. For each fee year after 2011, the IRS will determine a covered entity's total fee by applying, if applicable, the adjustment amount described in paragraph (e) of this section to the entity's allocated fee described in paragraph (d) of this section.

(2) *Calculation of branded prescription drug sales.* Each covered entity's allocated fee for any fee year is equal to an amount that bears the same ratio to the applicable amount as the covered entity's branded prescription drug sales taken into account during the sales year bears to the aggregate branded prescription drug sales of all covered entities taken into account during the sales year.

(3) *Applicable amount.* The applicable amounts for fee years are—

Fee year	Applicable amount
2011	$2,500,000,000
2012	2,800,000,000
2013	2,800,000,000
2014	3,000,000,000
2015	3,000,000,000
2016	3,000,000,000
2017	4,000,000,000
2018	4,100,000,000
2019 and thereafter	2,800,000,000

(3) *Sales taken into account.* A covered entity's branded prescription drug sales taken into account during any calendar year are as follows:

Covered entity's branded prescription drug sales during the calendar year that are:	Percentage of branded prescription drug sales taken into account is
Not more than $5,000,000	0
More than $5,000,000 but not more than $125,000,000	10
More than $125,000,000 but not more than $225,000,000	40
More than $225,000,000 but not more than $400,000,000	75
More than $400,000,000	100

(b) *Determination of branded prescription drug sales.* The IRS will compile each covered entity's branded prescription drug sales for each Program by NDC. Each NDC will be attributed to the covered entity that owns the NDC

as of the end of the day on December 31st of the sales year. For a covered entity that is a controlled group, this includes all NDCs that a member of the covered entity owns as of the end of the day on December 31st of the sales year. For this purpose, the IRS may revise the list of NDCs as a result of information received in the dispute resolution process, and the data the IRS uses to produce the final fee calculation will include any revisions provided by the Agencies at the completion of the dispute resolution process. Each covered entity's branded prescription drug sales will be reduced by its Medicare Part D rebates and Medicaid state supplemental rebate amounts in the following manner. If CMS has the rebate information for these Programs for a sales year, CMS will report to the IRS branded prescription drug sales net of rebates. If CMS does not have the rebate information for these programs for a sales year, the IRS will reduce the branded prescription drug sales reported for these Programs by rebates reported by the covered entities on Forms 8947.

(c) *Determination of sales taken into account.* (1) For each sales year and for each covered entity, the IRS will calculate sales taken into account. The resulting number is the numerator of the ratio described in paragraph (d)(1) of this section.

(2) For each sales year, the IRS will calculate the aggregate branded prescription drug sales taken into account for all covered entities. The resulting number is the denominator of the ratio described in paragraph (d)(2) of this section.

(d) *Allocated fee calculation.* For each covered entity for each fee year, the IRS will calculate the entity's allocated fee by multiplying the applicable amount from paragraph (a)(2) of this section by a fraction—

(1) The numerator of which is the covered entity's branded prescription drug sales taken into account during the sales year (described in paragraph (c)(1) of this section); and

(2) The denominator of which is the aggregate branded prescription drug sales taken into account for all covered entities during the same year (described in paragraph (c)(2) of this section).

(e) *Adjustment amount.* For each fee year after 2011, in addition to the allocated fee computed under paragraph (d) of this section, the IRS will also calculate an adjustment amount that reflects the difference between the allocated fee determined for the covered entity in the immediately preceding fee year, using data from the second calendar year preceding that fee year, and what the allocated fee would have been for that entity for the immediately preceding fee year using data from the calendar year immediately preceding that fee year. For example, for 2012, the adjustment amount for a covered entity will be the difference between the entity's 2011 allocated fee, using 2009 data, and what the 2011 allocated fee would have been using 2010 data. Although the adjustment reflects a revision of the prior year's fee based on data from the year immediately preceding the prior fee year, the adjustment is only taken into account by adding it to or subtracting it from the allocated fee computed under paragraph (d) of this section for the current fee year to arrive at the total fee for the current fee year.

§51.6T Notice of preliminary fee calculation (temporary).

(a) *Content of notice.* For each sales year, the IRS will make a preliminary calculation of the fee for each covered entity as described in §51.5T. The IRS will notify each covered entity of its preliminary fee calculation for that sales year. The notification to a covered entity of its preliminary fee calculation will include—

(1) The covered entity's allocated fee;

(2) The covered entity's branded prescription drug sales, by NDC, by Program;

(3) The covered entity's branded prescription drug sales taken into account after application of §51.5T(a)(3);

(4) The aggregate branded prescription drug sales taken into account for all covered entities;

(5) After the 2011 fee year, the covered entity's adjustment amount calculated as described in §51.5T(e); and

(6) A reference to the fee dispute resolution procedures set forth in guidance published in the Internal Revenue Bulletin.

(b) *Time of notice.* The IRS will send each covered entity notice of its preliminary fee calculation by the date prescribed in guidance published in the Internal Revenue Bulletin.

§ 51.7T Dispute resolution process (temporary).

(a) *In general.* Upon receipt of its preliminary fee calculation, each covered entity will have an opportunity to dispute this calculation by submitting to the IRS an error report as described in this section. The IRS will provide its final determination with respect to error reports no later than the time the IRS provides a covered entity with a final fee calculation.

(b) *Program errors.* To assert that there has been one or more errors in drug sales data, a covered entity must submit a separate error report for each Program with the asserted errors. Each report must include the following information—

(1) Entity name, entity number (if applicable, from Part I (a) of the Form 8947), address, and Employer Identification Number (EIN) as previously reported on the Form 8947;

(2) The name, telephone number, and e-mail address (if available) of one or more employees or representatives of the entity with whom the Agencies may discuss the claimed errors. A Form 2848, ''Power of Attorney and Declaration of Representative,'' must be filed with the error report; and

(3) The name of the Program that reported the data, the NDC, the specific amount of sales data disputed, the proposed corrected amount, an explanation of why the Agency should use the proposed corrected data instead, and documentation of any Program drug sales data or other information used to establish the existence of any errors.

(c) *Errors other than Program drug sales errors.* To assert that there has been one or more errors in the mathematical calculation of the fee, the rebate data, the listing of an NDC for an orphan drug, or any other error (other than Program drug sales data errors), a covered entity must submit one error report, separated into sections by type of error, and must include the following information—

(1) Entity name, entity number (if applicable, from Part I (a) of the Form 8947), address, and EIN as previously reported on the Form 8947;

(2) The name, telephone number, and e-mail address (if available) of one or more employees or representatives of the entity with whom the IRS and/or the Agencies may discuss the claimed errors. A form 2848 must be filed with the error report;

(3) For a mathematical calculation error, the specific calculation element(s) that the entity disputes and its proposed corrected calculation;

(4) For a rebate data error, the NDC for the drug to which it relates; a discussion of whether the data used in the preliminary fee calculation matches previously reported Form 8947 data on rebates; and, if the data used in the preliminary fee calculation does match the Form 8947 data, an explanation of why the Form 8947 data was erroneous and why the IRS should use the proposed corrected data instead;

(5) For the listing of an NDC for an orphan drug, the name and NDC of the orphan drug; a discussion of whether the data used in the preliminary fee calculation matches previously reported Form 8947 data on orphan drugs; and, if the data used in the preliminary fee calculation does match the Form 8947 data, an explanation of why the Form 8947 data was erroneous and why the IRS should use the proposed corrected data instead;

(6) For any other asserted error, an explanation of the nature of the error, how the error affects the fee calculation, an explanation of how the entity established that an error occurred, the proposed correction to the error, and an explanation of why the IRS or Agency should use the proposed corrected data instead;

(7) If an entity is using data to establish the existence of an error and that data was not reported on Form 8947 or contained in the notification of the preliminary fee calculation, a description of what the data is, how the entity acquired the data, and who maintains it; and

(8) Documentation of any rebate and orphan drug data, or other information used to establish the existence of any errors.

(d) *Form, manner, and timing of submission.* Each covered entity must submit its error report(s) in the form and manner that is prescribed in guidance published in the Internal Revenue Bulletin. This guidance will also prescribe the date by which each covered entity must submit its report(s).

[T.D. 9544, 76 FR 51249, Aug. 18, 2011; 76 FR 59897, Sept. 28, 2011]

§ 51.8T Notification and payment of fee (temporary).

(a) *Notification of final fee calculation.* No later than August 31st of each fee year, the IRS will send each covered entity its final fee calculation for that year. In any fee year, the IRS will base its final fee calculation on data provided to it by the Agencies as adjusted pursuant to the dispute resolution process. The notification to a covered entity of its final fee calculation will include—

(1) The covered entity's allocated fee;

(2) After the 2011 fee year, the covered entity's adjustment amount calculated as described in § 51.5T(e);

(3) The covered entity's branded prescription drug sales, by NDC, by Program;

(4) The covered entity's branded prescription drug sales taken into account after application of § 51.5T(a)(3);

(5) The aggregate branded prescription drug sales taken into account for all covered entities; and

(6) The final determination with respect to error reports.

(b) *Differences in preliminary fee calculation and final fee calculation.* A covered entity's final fee calculation may differ from the covered entity's preliminary fee calculation because of changes made pursuant to the dispute resolution process described in § 51.7T. Even if a covered entity did not file an error report described in § 51.7T, a covered entity's final fee may differ from a covered entity's preliminary fee because of a change in data reported by the Agencies after resolution of error reports, including a change in the aggregate prescription drug sales figure. A change in aggregate prescription drug sales data can affect each covered entity's fee because each covered entity's fee is a fraction of the aggregate fee collected from all covered entities. A covered entity's final fee may also differ from its preliminary fee calculation because the data used in the preliminary fee calculation may have contained inaccurate branded prescription drug sales information that was corrected or updated at the conclusion of the dispute resolution process.

(c) *Payment of final fee.* Each covered entity must pay its final fee by September 30th of the fee year. For a controlled group, the payment must be made using the designated entity's EIN as reported on Form 8947. The fee must be paid by electronic funds transfer as required by § 51.6302–1T. There is no tax return to be filed for the fee.

(d) *Joint and several liability.* In the case of a controlled group that is liable for the fee, all covered entities within the controlled group are jointly and severally liable for the fee. Accordingly, if a covered entity's fee is not paid, the IRS will separately assess each covered entity in the group for the full amount of the controlled group's fee.

[T.D. 9544, 76 FR 51249, Aug. 18, 2011; 76 FR 59897, Sept. 28, 2011]

§ 51.9T Tax treatment of fee (temporary).

(a) *Treatment as an excise tax.* The fee imposed by section 9008 is treated as an excise tax for purposes of subtitle F of the Code (sections 6001–7874). Thus, references in subtitle F to ''taxes imposed by this title,'' ''internal revenue tax,'' and similar references, are also references to the fee imposed by section 9008. For example, the fee imposed by section 9008 is assessed (section 6201), collected (sections 6301, 6321, and 6331), enforced (section 7602), subject to examination and summons (section 7602), and subject to confidentiality rules (section 6103), in the same manner as taxes imposed by the Code.

(b) *Deficiency procedures.* The deficiency procedures of sections 6211–6216 do not apply to the fee imposed by section 9008.

(c) *Limitation on assessment.* The IRS must assess the amount of the fee for

any fee year within three years of September 30th of that fee year.

(d) *Application of section 275.* The fee is treated as a tax described in section 275(a)(6) (relating to taxes for which no deduction is allowed).

§ 51.10T Refund claims (temporary).

Any claim for a refund of the fee must be made by the person that paid the fee to the government and must be made on Form 843, ''Claim for Refund and Request for Abatement,'' in accordance with the instructions for that form.

§ 51.11T Effective/applicability date (temporary).

Sections 51.1T through 51.10T apply to any fee on branded prescription drug sales that is due on or after September 30, 2011.

§ 51.12T Expiration date (temporary).

The applicability of §§ 51.1T through 51.10T expires August 15, 2014.

§ 51.6302–1T Method of paying the branded prescription drug fee (temporary).

(a) *Fee to be paid by electronic funds transfer.* Under the authority of section 6302(a), the fee imposed on branded prescription drug sales by section 9008 and § 51.5T must be paid by electronic funds transfer as defined in § 31.6302–1(h)(4)(i), as if the fee were a depository tax. For the time for paying the fee, see § 51.8T.

(b) *Effective/applicability date.* This section applies on and after *August 18, 2011.*

(c) *Expiration date.* The applicability of this section expires August 15, 2014.

PART 52—ENVIRONMENTAL TAXES

AUTHORITY: 26 U.S.C. 7805.

Section 52.4682–3 also issued under 26 U.S.C. 4682(c)(2);

Section 52.4682–5 also issued under 26 U.S.C. 4662(e)(4).

§ 52.0–1 Introduction.

The regulations in this part 52 are designated ''Environmental Tax Regulations.'' The regulations relate to the environmental taxes imposed by chapter 38 of the Internal Revenue Code. See part 40 of this chapter for regulations relating to returns, payments, and deposits of taxes imposed by chapter 38.

[T.D. 8442, 57 FR 48186, Oct. 22, 1992]

§ 52.4681–1 Taxes imposed with respect to ozone-depleting chemicals.

(a) *Taxes imposed.* Sections 4681 and 4682 impose the following taxes with respect to ozone-depleting chemicals (ODCs):

(1) *Tax on ODCs.* Section 4681(a)(1) imposes a tax on ODCs that are sold or used by the manufacturer or importer thereof. Except as otherwise provided in § 52.4682–1 (relating to the tax on ODCs), the amount of the tax is equal to the product of—

(i) The weight (in pounds) of the ODC;

(ii) The base tax amount (determined under section 4681(b)(1) (B) or (C)) for the calendar year in which the sale or use occurs; and

(iii) The ozone-depletion factor (determined under section 4682(b)) for the ODC.

(2) *Tax on imported taxable products.* Section 4681(a)(2) imposes a tax on imported taxable products that are sold or used by the importer thereof. Except as otherwise provided in § 52.4682–3 (relating to the tax on imported taxable products), the tax is computed by reference to the weight of the ODCs used as materials in the manufacture of the product. The amount of tax is equal to the tax that would have been imposed on the ODCs under section 4681(a)(1) if the ODCs had been sold in the United States on the date of the sale or use of the imported product. The weight of such ODCs is determined under § 52.4682–3.

(3) *Floor stocks tax*—(i) *Imposition of tax.* Section 4682(h) imposes a floor stocks tax on ODCs that—

(A) Are held by any person other than the manufacturer or importer of the ODC on a date specified in paragraph (a)(3)(ii) of this section; and